



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,024	05/15/2007	Elzbieta Mietkiewska	PAT 989W-2	1829

26123 7590 09/29/2009
BORDEN LADNER GERVAIS LLP
Anne Kinsman
WORLD EXCHANGE PLAZA
100 QUEEN STREET SUITE 1100
OTTAWA, ON K1P 1J9
CANADA

EXAMINER

KUMAR, VINOD

ART UNIT	PAPER NUMBER
----------	--------------

1638

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

09/29/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipinfo@blgcanada.com

Office Action Summary	Application No. 10/596,024	Applicant(s) MIETKIEWSKA ET AL.	
	Examiner VINOD KUMAR	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 5/25/06 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Status of objections and rejections

1. Claims 1-23 are pending. Claims 1-23 are examined on merits in the present Office action.

Information Disclosure Statement

2. The listing of references in the specification (pages 34-35) is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

The disclosure is objected to because of the following informalities:

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See for example, page 24, line 27.

Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

4. Applicant is required to provide reference to the prior-filed US application in the first sentence(s) of the specification.

5. The abstract of disclosure is objected to because of the following informalities:

Abstract recites “said” at several places. See for example, lines 4-6 and 9. The legal phraseology often used in patent claims, such as “said” in the instant case should be avoided. See MPEP § 608.01(b).

6. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. For example, Sequence identifiers are missing from page 13, lines 3-4.

Description of drawing does not have SEQ ID listed with the sequences. For example, the sequences in figure 2A must be referred to by their sequence identifiers in description of drawings to comply with 37 CFR 1.821 through 1.825.

If the sequences appearing in the specification do not have sequence ID numbers assigned to them, then an amendment to the sequence listing will be required as well. There must not be any new matter submitted, therefore it is important to be careful to include only the sequences that are already disclosed in the current specification.

Appropriate action is required.

Drawings

The drawings are objected to because of the following informalities:

Drawings are objected to because they fail to comply with 37CFR 1.83.

Art Unit: 1638

7. Figures 5A, 5B and 8 fail to comply with 37 CFR 1.84(g) because these figures are framed. Applicant is requested to delete the frames to comply with 37 CFR 1.84(g).

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Appropriate action is requested.

Claim Objections

8. Claims 16-20 and 21 are objected to because of the following informalities:

Claims 2 and 3 are objected for having improper article before “plant fatty acid” in line 1. It is suggested to change “a” to --the-- or --said--.

In claim 5, it is suggested to recite expression of the heterologous gene.

Claims 12 and 13 are objected for having improper article before “plant cell” in line 1. It is suggested to change “A” to --The--.

Claims 16-20 are objected for having improper article before “plant” in line 1. It is suggested to change “A” to --The--.

Claim 18 is objected for lacking space between “the” and “*Limnanthaceae*”.

Claim 18 is objected for reciting “*Limnanthaceae* or *Tropaeolaceae* or *Simmondsia*” which does not ready properly. It is suggested to change “*Limnanthaceae* or *Tropaeolaceae* or *Simmondsia*” to --*Limnanthaceae*, *Tropaeolaceae* or *Simmondsia* family--.

Claim 21 is objected for using improper article before “plant” in line 2. It is suggested to change “cultivating a plant according to claim 15 and then extracting a plant-derived oil therefrom which has altered erucic acid content” to --cultivating the plant of claim 15 and then extracting oil from said plant, wherein said oil has altered erucic acid content--.

Appropriate corrections are required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5, 10, 12, 22 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in their recitation "gene" which is confusing since the limitation "gene" implies that the structure comprises the coding sequence and the associated promoter, terminator and enhancer encoding regions are also a part of the structure (see The Federal Register, Vol. 66, No. 4, Friday, January 5, 2001 at page 1108, left column, Endnote 13). In the instant case, Applicants do not appear to describe such gene(s) associated nucleic acid sequences. It is suggested that "gene" be amended to --coding sequence--.

Claims 1, 5, 11, 13 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in their recitation "very" because the term "very" is a relative term which renders the claim indefinite. The term "very" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bounds of the recitation are unclear as they are not defined.

Claims 11 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite because it is unclear what is in parenthesis is intended to be a claim limitation.

Dependent claims are also rejected because they fail to overcome the deficiencies of parent claims.

Claim Rejections - 35 USC § 112 and 101

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 22-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 provides for the use of a heterologous plant fatty acid elongase gene for altering erucic acid content in a plant, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 23 provides for the use of a heterologous plant fatty acid elongase gene for altering very long chain fatty acid content in a plant, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 22-23 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under

Art Unit: 1638

35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and

Art Unit: 1638

that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Id.*

See also MPEP Section 2163, page 174 of Chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Claims are broadly drawn to an expression vector for transforming a cell, said expression vector comprising a gene coding for a plant fatty acid elongase in reading frame alignment with a promoter capable of increasing expression of said gene, when said transformed cell is in a seed, sufficient to increase the proportion of very long chain monounsaturated fatty acid when compared with a control cell, or wherein said gene coding for a plant fatty acid elongase is a *Nasturtium* fatty acid elongase gene, or wherein said gene coding for a plant fatty acid elongase is a *Crambe* fatty acid elongase gene, or wherein said gene coding for a plant fatty acid elongase is an

Art Unit: 1638

Arabidopsis fatty acid elongase gene, or a cell comprising a heterologous gene coding for a heterologous plant fatty acid elongase or allelic variant thereof, said cell being capable of producing an increase in proportion of a very long chain monounsaturated fatty acid when compared a control cell lacking said heterologous gene, or wherein said cell is a fungal cell, or wherein said fungal cell is a yeast cell, or wherein said cell is a plant cell, or wherein said cell is a plant seed cell, or wherein said plant cell additionally comprising a further heterologous gene coding for an additional heterologous plant fatty acid elongase or allelic variant thereof or a heterologous plant desaturase gene or allelic variant thereof, or wherein said plant is capable of producing oil with an increased content of erucic acid or other very long chain fatty acid (C20 or greater), or wherein said heterologous gene codes for a 3-ketoacyl-CoA synthase, or wherein said very long chain monounsaturated fatty acid comprises erucic acid, a seed comprising a plurality of said plant cells, or wherein said plant is a dicotyledon, or wherein said plant is a member of the *Brassicaceae*, or wherein said plant is a member of the *Limnanthaceae* or *Tropaeolaceae* or *Simmondsia*, or wherein said plant is flax (*Linum usitatissimu* L.), or wherein said plant is of the *Brassica* genus, a method for altering erucic acid content of a plant-derived oil which method comprises cultivating said plant and then extracting a plant-derived oil therefrom which oil has altered erucic acid content, or use of a heterologous plant fatty acid elongase gene for altering erucic acid content in a plant, or use of a heterologous plant fatty acid elongase gene for altering the very long chain fatty acid content (C20 or greater) in a plant.

Art Unit: 1638

The essential feature of claim 1 is any plant fatty acid elongase that has the ability to increase the proportion of very long chain monounsaturated fatty acid in a plant.

The essential features of claim 2 is any fatty acid elongase derived from *Nasturtium* that has the ability to increase the proportion of very long chain monounsaturated fatty acid in a plant.

The essential features of claim 3 is any fatty acid elongase derived from *Crambe* that has the ability to increase the proportion of very long chain monounsaturated fatty acid in a plant.

The essential features of claim 4 is any fatty acid elongase derived from *Arabidopsis* that has the ability to increase the proportion of very long chain monounsaturated fatty acid in a plant.

The essential feature of claims 5 and 10 is an allelic variant of any plant fatty acid elongase that has the ability to increase the proportion of very long chain monounsaturated fatty acid in a plant.

The essential feature of claims 10 is any plant desaturase the ability to increase the proportion of very long chain monounsaturated fatty acid in a plant.

The essential feature of claims 10 is an allelic variant of any plant desaturase the ability to increase the proportion of very long chain monounsaturated fatty acid in a plant.

The essential feature of claim 22 is any plant fatty acid elongase gene that has the function of altering erucic content in a plant.

The essential feature of claim 23 is any plant fatty acid elongase gene that has the function of altering very long chain fatty acid content in a plant.

The instant specification, however, only describes an elongase gene encoding *Tropaeolum majus* elongase as shown in SEQ ID NO: 22, an elongase gene encoding *Crambe abyssinica* elongase as shown in SEQ ID NO: 24 and an *Arabidopsis* elongase as shown in SEQ ID NO: 26. The instant specification also describes *Nasturtium* FAE (SEQ ID NO: 22) overexpression in the seeds of *Brassica carinata* resulted in almost 39% increase in erucic content. The instant specification also describes *Limnanthes* desaturase gene (GenBank accession NO. AF247133) co-expressed with *Nasturtium* FAE (SEQ ID NO: 22) resulted in the accumulation of long chain monounsaturated fatty acid. See in particular, examples 9-10, pages 17-18; figures 6 and 8.

The specification does not describe fatty acid elongases from different plant sources and thus their function of increasing very long chain monounsaturated fatty acids in plants is unknown.

The specification does not describe fatty acid elongases from different plant sources and thus their function of increasing erucic acid in plants is unknown.

The specification does not describe fatty acid elongases from a genus of *Tropaeolum* species and thus their function of increasing very long chain monounsaturated fatty acids or erucic acid in plants is unknown.

The specification does not describe fatty acid elongases from a genus of *Crambe* species and thus their function of increasing very long chain monounsaturated fatty acids erucic acid in plants is unknown.

The specification does not describe fatty acid elongases from a genus of *Arabidopsis* species and thus their function of increasing very long chain monounsaturated fatty acids erucic acid in plants is unknown.

The specification fails to describe structure for allelic variants of plant elongase genes and thus their function of increasing very long chain monounsaturated fatty acids or erucic acid is unknown.

The specification fails to describe structure for allelic variants of plant desaturase genes and thus their function of increasing very long chain monounsaturated fatty acids or erucic acid is unknown.

There is no description of the structure required for the recited function, and no description of the necessary and sufficient elements of functional activity (increasing erucic content) of SEQ ID NO: 22.

There is no description of the structure required for the recited function, and no description of the necessary and sufficient elements of functional activity (increasing very long chain monounsaturated fatty acids) of *Limnanthes* desaturase gene (GenBank accession NO. AF247133).

While any step in a metabolic pathway can be made to control flux if the step is blocked, increasing the activity of an enzyme may not necessarily result in an increased flux through the reaction it catalyses. See for example, Kinney et al. (Biochemical Society Transactions; 30: 1099-1103; 2002) who describe that overexpression of stearyl-ACP desaturase cDNA in transgenic soybean embryos did not result in any change in the fatty acid content of triacylglycerol. See in particular, page 1100, right

Art Unit: 1638

column, 1st paragraph. Also see Joubes et al. (Plant Mol. Biol., 67:547-566, 2008) who suggest that expression patterns in *Arabidopsis* of the acyl-CoA elongase genes undergo several levels of regulations at tissue or organ level because of complex organization of elongase multigene family. See in particular, abstract.

Thus, Applicant's broadly claimed genus of elongases and desaturases encompasses structures whose function of increasing the proportion of very long chain monounsaturated fatty acid and/or erucic acid content in a plant would not be reliably predicted. Thus, Applicant's broadly claimed genus encompasses structures whose function is unrelated to SEQ ID NO: 22 or *Limnanthes* desaturase gene (GenBank accession NO. AF247133).

One of skill in the art would not recognize that Applicant was in possession of the necessary common attributes or features of the genus in view of the disclosed species. Since the disclosure fails to describe the common attributes that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 22 or *Limnanthes* desaturase gene (GenBank accession NO. AF247133) is insufficient to describe the claimed genus.

Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/Vol.66, No. 4/Friday, January 5, 2001/Notices; p. 1099-1111.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide written description of the genus broadly claimed.

Art Unit: 1638

Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1, 4-5, 7-17 and 20-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Katavic et al. (Biochemical Society Transactions; 28 (part 6): 935-937; 2000).

Katavic et al. disclose a method for altering erucic acid (very long monounsaturated fatty acid) and oil content in rapeseed (*Brassica napus*), comprising transformation of plant cells with an *Arabidopsis* FAE1 or yeast SLC1-1 gene under the control of a seed-specific napin promoter. The reference also describes transgenic seeds and progenies derived thereof. The reference also discloses combination of the two genes into *Brassica napus* by crossing between FAE1 *B. napus* Hero and SLC1-1 *B. napus* Hero transgenic lines. See in particular, page 935, abstract; page 936, table 1, figure 1; page 937, table 2.

Accordingly Katavic et al. anticipated the claimed invention.

Art Unit: 1638

13. Claims 1, 4-17 and 20-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Katavic et al. (Crop Sci. 41:739-747, 2001).

Katavic et al. disclose a method for altering erucic acid (very long monounsaturated fatty acid) and oil content in rapeseed (*Brassica napus*), comprising transformation of plant cells with an *Arabidopsis* FAE1 or yeast SLC1-1 gene under the control of a seed-specific napin promoter. The reference also describes transgenic seeds and progenies derived thereof. The reference also discloses combination of the two genes into *Brassica napus* by crossing between FAE1 *B. napus* Hero and SLC1-1 *B. napus* Hero transgenic lines. The reference also describes expression of *Arabidopsis* FAE1 gene in yeast cells. See in particular, page 739, abstract; page 740, figure 1; page 742, figures 2 and 3; page 743, figure 4; page 744, tables 1-3, figure 5; page 745, figures 6-7; discussion.

Accordingly Katavic et al. anticipated the claimed invention.

14. Claims 1, 4-9 and 12-23 are rejected under 35 U.S.C. 102(b) as being anticipated by James et al. (CA 2,203,754 (WO 96/13582), Issued May 9, 1996).

James et al. describe polynucleotide sequences from both the *Arabidopsis* FAE1 gene and *B.napus* FAE1 gene. The reference further describes DNA constructs comprising the polynucleotide sequences that are used to modify FAE1 gene expression and thereby modulating fatty acid content in plant organs, particularly seeds. The reference further describes transgenic plants (*Brassica* plants) comprising a recombinant expression cassette which includes a plant promoter operably linked to the polynucleotide sequence disclosed in the reference. The reference also discloses the

Art Unit: 1638

use of said DNA construct in broad range of plants including *Linum*, *Simmondsia* and *Limnathes*. The reference also discloses that FAE1 polypeptide may also be expressed in a microorganism host, such as bacteria or yeast. See in particular, page 8, line 21 through page 9, line 3; page 10, lines 26-27; claims 1-26.

Accordingly, James et al. anticipated the claimed invention.

15. Claims 1, 2, 4, 5, 8-17 and 20-23 are rejected under 35 U.S.C. 102(a) as being anticipated by Wilmer et al. (CA 2,463,166 A3 (WO2003/033713); Issued April 24, 2003).

Wilmer et al. describe a method for producing in a plant, an oil having an erucic acid content above 66% by expressing an heterologous nucleic acid encoding an elongase and a nucleic acid encoding an acyltransferase enzyme. The reference also describes transgenic expression of *Brassica napus* FAE1 and FAE1-2, or similar enzymes from *Arabidopsis* and *Nasturtium* to increase erucic acid content. The reference also describes a plant transformation vector comprising an expression cassette having said heterologous nucleic acids. See in particular, figures 1-7; claims 1-17; description (pages 1-21).

Accordingly Wilmer et al. anticipated the claimed invention.

16. Claims 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Wienand et al. (CA 2,337,980 (WO 2000/008172); Issued February 17, 2000).

Weinand et al. describe a yeast cell comprising a heterologous gene coding for a plant fatty acid elongase. The reference further describes increase in long chain

Art Unit: 1638

monounsaturated fatty acid in said host cell. See in particular, claims 1-2; pages 1-37 of description; example 4.

It is important to note that the property of increasing very long chain monounsaturated fatty acid would also be inherent to the expression of elongase in the host cell disclosed in the reference.

Accordingly, Weinand et al. anticipated the claimed invention.

17. Claims 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Jaworski et al. (CA 2,292,770 (WO 1998/054954); Issued December 10, 1998; Applicant's search report PCT).

Jaworski et al. describe a yeast cell comprising a heterologous gene coding for a plant fatty acid elongase. The reference further describes increase in long chain monounsaturated fatty acid in said host cell. See in particular, claims 1-30; pages 1-52 of description; examples 1-2.

It is important to note that the property of increasing very long chain monounsaturated fatty acid would also be inherent to the expression of elongase in the host cell disclosed in the reference.

Accordingly, Jaworski et al. anticipated the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 1638

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claim 3 rejected under 35 U.S.C. 103(a) as being unpatentable over James et al. (CA 2,203,754 (WO 96/13582), Issued May 9, 1996).

James et al. teach polynucleotide sequences from both the *Arabidopsis* FAE1 gene and *B.napus* FAE1 gene. The reference further teaches DNA constructs comprising the polynucleotide sequences that are used to modify FAE1 gene expression and thereby modulating fatty acid content in plant organs, particularly seeds. The reference further teaches transgenic plants (*Brassica* plants) comprising a recombinant expression cassette which includes a plant promoter operably linked to the polynucleotide sequence taught in the reference. The reference also teaches the use of said DNA construct in broad range of plants including *Linum*, *Simondsia* and *Limnathes*. The reference also teaches that FAE1 polypeptide may also be expressed in a microorganism host, such as bacteria or yeast. See in particular, page 8, line 21 through page 9, line 3; page 10, lines 26-27; claims 1-26.

Art Unit: 1638

James et al. do not teach *Nasturtium* fatty acid elongase gene.

Given the use of elongase enzymes from *Arabidopsis*, *Brassica* and other plant species share identical enzymatic activities for modulating fatty acid content in a plant as asserted by James et al., it would have been obvious and within the scope of an ordinary skill in the art to have used any fatty acid elongase gene including *Nasturtium* fatty acid gene as a part of normal design procedure and regardless of its source in modulating fatty acid content in a plant, and thus arrive at the claimed invention with a reasonable expectation of success.

Thus, the claimed invention as a whole is prima facie obvious over the teachings of the prior art.

Conclusions

20. Claims 1-23 are rejected.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-5444. The examiner can normally be reached on 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Vinod Kumar/
Examiner, Art Unit 1638